NEW STUDY SHOWS EXCELLENT ACCURACY OF BARD1-OVARIAN IN HIGH-RISK WOMEN

- **BARD1-Ovarian test shows excellent accuracy for detection of ovarian cancer in high-risk women**
- **New results show higher sensitivity in high-risk women with a family history of breast/ ovarian cancer or carrying BRCA1/2 mutations**
- **Validates commercial potential as a screening test for ovarian cancer in high-risk women to detect ovarian cancer early, save women's lives and avoid unnecessary surgery**
- **Breakthrough provides further impetus to progress to clinical studies**

Perth, Australia, 6 September 2018: BARD1 Life Sciences Limited (ASX:BD1), a biotechnology company developing non-invasive cancer diagnostics, is pleased to announce important new research showing high accuracy of its improved BARD1-Ovarian for detection of ovarian cancer in high-risk women.

This new study shows that BARD1-Ovarian has high accuracy for detection of ovarian cancer in high-risk women with a family history of breast/ovarian cancer or carrying inherited BRCA1/2 mutations, which predispose women to breast and ovarian cancer.

These new results enhance the commercial potential of BARD1-Ovarian as an effective screening test for national healthcare systems. Importantly, these results build on previous research and further support advancing BARD-Ovarian into clinical studies to evaluate its clinical performance as a screening test for ovarian cancer to detect ovarian cancer early, save women's lives and avoid unnecessary surgery.

Corporate opportunities

The research findings also open a range of corporate and financial opportunities for BARD1 to optimise the commercialisation pathway and maximise value for shareholders.

The Company expects further product development will take approximately two years if future clinical studies deliver expected positive results enabling the company to launch BARD1-Ovarian as a laboratory developed test in Australia and the USA by 2021.

BARD1 will make announcements on these developments at the appropriate time.

Currently the generic CA125 blood test is widely used as an ovarian cancer test in Australia and around the world but has less than 50% sensitivity for detection of early-stage ovarian cancer.

In June this year, the company announced that the improved BARD1-Ovarian test (combining BARD1 autoantibodies and CA125) delivered excellent diagnostic accuracy of 0.95 AUC, with 88% sensitivity (detection) and 93% specificity (low false positives) for detection of ovarian cancer in a group of 400 average-risk women – half of whom had ovarian cancer.

These latest results uphold the accuracy of the improved BARD1-Ovarian as being even better for early detection of ovarian cancer in high-risk women who have Hereditary Breast and Ovarian Cancer Syndrome (HBOC). These are women with a family history of breast/ovarian cancer or that carry the *BRCA1/2* gene mutations that predispose to cancer.

BRCA1/2 mutations are responsible for about 10 to 15 percent of all ovarian cancers. A woman's lifetime risk of developing ovarian cancer in the general population (average-risk women) is 1.3%, whereas in *BRCA1* mutation carriers the lifetime risk of developing ovarian, fallopian tube or peritoneal cancer is 35-70% and in *BRCA2* mutation carriers it is 10-30%.[1]

Tapping into fast-growing global demand

BARD1 is targeting the burgeoning global market for early detection of cancer that has flowed from advances in genetic science and the exponential growth in gene mapping by individuals in the developed world.

Genetic testing can now identify at-risk individuals with predisposition genes, and close monitoring of early-stage tumour development is needed for women identified as mutation carriers. It is generally accepted that individuals with a family history of of breast/ovarian cancers should undergo *BRCA1/2* mutation genetic screening, and that regular monitoring of mutation positive women is needed. However, available screening procedures include mammography for detection of breast cancer, whereas no accurate and reliable ovarian cancer screening test exists.

The Company will look to gain a strong presence in both routine screening programs and in the fast-growing personalised medicine market where people want knowledge and are willing to pay privately to secure this.

“As people have become aware of their genetic make-up and pre-disposition to disease, they want to take action to protect their health,” said Dr Irmgard Irminger-Finger, BARD1 Executive Director and Chief Scientific Officer.

“For some, like Angelina Jolie, this means electing to undergo radical, preventative surgery. The great hope of medical science is that accurate testing can detect early stage cancer and deliver better health choices and outcomes to patients.”

“Most current tests for ovarian cancer are accurate only at later stages of the disease.”

“BARD1-Ovarian has demonstrated high accuracy to detect ovarian cancer at early stages and these latest research findings underline how significant the test can be in routine screening of high-risk women to improve survival and avoid unnecessary surgery.”

Excellent test accuracy among high-risk women

BARD1 conducted the OC-R001 study to evaluate and compare the accuracy of the BARD1-Ovarian test to detect ovarian cancer in high-risk women comprising 261 plasma samples of ovarian cancers from women with a family history of breast/ovarian cancers, or with mutations in BRCA1, BARD1 or other predisposition genes (BRCA2, NBN, Rad50, PALB2, ATM, CHEK2) compared to healthy controls.

The results demonstrated the high diagnostic accuracy of the improved BARD1-Ovarian test for detection of ovarian cancer in high-risk women across all cancer stages with an average AUC=0.99 in training sets, and an average AUC=0.97, 89% sensitivity and 97% specificity in the cross-validation test sets.

The sensitivity of BARD1-Ovarian for detection of ovarian cancer was highest in women with BRCA1/BARD1 mutations (showing 100% sensitivity at fixed 90% specificity) and was independent of cancer stage, which was expected as BARD1 forms a complex and acts together with BRCA1 in healthy people to suppress cancer. Table 1 summarises the results of the OC-R001 Study in high-risk women.

Table 1: BARD1-Ovarian test results in OC-R001 Study

Study	Samples	Training Sets*			Test Sets*		
	n (cancer:normal)	AUC	Sensitivity	Specificity	AUC	Sensitivity	Specificity
OC-R001[2]	281 (127:134)	0.99	98%	95%	0.97	89%	97%

* *Youden cutoff that maximises sensitivity and specificity*

The study concluded that the improved BARD1-Ovarian test showed high accuracy and could be further developed as a screening test for early detection of ovarian cancer in high-risk women with a family history of breast/ovarian cancer, or women identified with mutations in BRCA1/2 or other predisposition genes.

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ABOUT BARD1 LIFE SCIENCES LTD

BARD1 Life Sciences Ltd (ASX:BD1) is an Australian-based biotechnology company focused on developing and commercialising non-invasive diagnostic tests for early detection of cancer. BARD1's proprietary technology platform is based on novel tumour markers with potential diagnostic and therapeutic applications across multiple cancers. The development pipeline includes two BARD1 autoantibody tests in development for early detection of lung and ovarian cancers, and a cancer vaccine project at research-stage for treatment of cancer. Additional diagnostic projects are being evaluated for prostate, breast and other cancers. BARD1 is committed to transforming the early detection and prevention of cancer to help improve patients' lives. For more information on BARD1, see www.bard1.com.

ABOUT THE BARD1-OVARIAN TEST

BARD1-Ovarian is a blood test in development for early detection of ovarian cancer. The improved test measures BARD1 autoantibodies and CA125 in the blood and uses a proprietary diagnostic algorithm to combine these levels into a cancer score that identifies the presence or absence of ovarian cancer. BARD1-Ovarian could potentially be used as a screening test for early detection of ovarian cancer in high-risk asymptomatic women, or to aid diagnosis in symptomatic women.

ABOUT OVARIAN CANCER

Ovarian cancer is the leading cause of gynaecological cancer deaths and seventh most common cancer in women worldwide, with around 239,000 new cases diagnosed and 152,000 deaths in 2012.[3] Ovarian cancer is often diagnosed at a late stage after symptoms have appeared, resulting in a poor prognosis with an overall 5-year survival rate of 46% in the US, and recurrence of around 70% after 12-18 months. Earlier detection by finding ovarian cancer when local rather than distant may increase 5-year survival from 29% to 92%, a potential survival improvement of 3 times. There is a clear unmet clinical need for non-invasive, accurate and affordable diagnostic tests for the early detection and monitoring of ovarian cancer. The global ovarian cancer diagnostics market was valued at US$7.2B in 2013 and is expected to grow at 7.2% annually to reach US $11.8B by 2020.[4]

ABOUT DIAGNOSTIC TEST RESULTS

The performance of a diagnostic test can be measured by "AUC", "sensitivity" and "specificity". AUC (area under the curve) is an overall score of diagnostic accuracy generated by a ROC (receiver operating characteristic) curve, where a perfect test would have an AUC=1.0, an excellent test AUC=0.9-0.99, a good test AUC=0.8-0.89, and a useless test AUC=0.5. Sensitivity is the percent of patients with cancer correctly identified positive (true positive rate) and specificity refers to the percent of patients without cancer correctly identified negative (true negative result). A good diagnostic test must demonstrate acceptable sensitivity and false positives rates for its intended use.

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[1] ACS 2018, *Ovarian Cancer Risk Factors*, ACS, accessed 5 September 2018, <https://www.cancer.org/cancer/ovarian-cancer/causes-risks-prevention/risk-factors.html>
[2] BARD1 LSL. OC-R001 Study. Data on file. Sep 2018
[3] Ferlay J, et al. GLOBOCAN 2012 v1.0, Estimated Incidence, Mortality and 5-year Prevalence: IARC CancerBase No. 11 [Internet]. Lyon, France: IARC; 2013. Available: http://globocan.iarc.fr/Pages/fact_sheets_population.aspx
[4] Transparency Market Research (2014, Oct 31). *Cancer Diagnostics Market: Global Industry Analysis, Size, Share, Growth, Trends, Forecast, 2014 - 2020*. Available http://www.transparencymarketresearch.com/cancer-diagnostics-market.html, accessed October 15, 2016.